K003246

DEC 21 2000

Special 510(k): Device Modification
MultiView WorkStation & INFINITY Network with the INFINITY VentViewer Option

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510(k) SUMMARY
as required per 807.92(c)

Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Establishment Registration Number: 1220063
Official Correspondent: David Simard, Director, QA/RA
Contact person for this submission: Penelope H. Greco
Date submission was prepared: October 11, 2000

Trade Name, Common Name and Classification Name:

A. Trade Name:
MultiView WorkStation and INFINITY Network

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
System, Network and Communication, Physiological Monitors	MSX		
Monitor, Physiological, Patient (with Arrhythmia Detection Or Alarms)	MHX	III	21 CFR 870.1025
Cardiac monitor	74DRT	II	21 CFR 870.2300
Pulse rate monitor	74BWS	II	21 CFR 870.2300
Pulse oximeter	74DQA	II	21 CFR 870.2700
Breathing Frequency Monitor	73BZQ	II	21 CFR 868.2375
Clinical Electronic Thermometer	80BWX	II	21 CFR 880.2910
Indwelling Blood Pressure Monitor	74CAA	II	21 CFR 870.1110
Heart Rate Monitor, Neonatal	74FLO	II	21 CFR 870.2300
Ventilatory Effort Monitor (Apnea Detector)	73FLS	II	21 CFR 868.2375
Monitor Blood Pressure, Neonatal, Invasive	74FLP	II	21 CFR 870.1110
Arrhythmia detector & Alarm	74DSI	III	21 CFR 870.1025
Medical Cathode-Ray Tube Display	74DXJ	II	21 CFR 870.2450
ST Segment Monitor with Alarm	74MLD	III	21 CFR 870.1025
Non-indwelling Blood Pressure Monitor	74DXN	II	21 CFR 870.1130
End-tidal Carbon-Dioxide Monitor	73CCK	II	21 CFR 868.1400

Legally Marketed Device Identification:
K955059 Olympus Communications Network, SC 3000 WorkStation and Remote Display

Description of Modification:
The MultiView WorkStation (MVWS) & INFINITY Network were submitted as the Olympus Communications Network, SC 3000 WorkStation and Remote Display, 510(k) K 955059.

Special 510(k): Device Modification
MultiView WorkStation & INFINITY Network with the INFINITY VentViewer Option

The INFINITY VentViewer™ option for the MVWS will provide clinicians with the capability of viewing ventilator data on the MultiView WorkStation (central station). The VentViewer will also provide both audible and visual ventilator alarm information at the MVWS

The VentViewer provides clinicians with a summary of data for a ventilated patient that includes simultaneous viewing of flow, pressure and volume data. The VentViewer screen functions as a second BedView in the MultiView WorkStation and is configurable for the display of ventilator real-time waves, two real-time loops and ventilator trends. The user has the ability to determine the configuration of the VentView screen.

Intended Use:
The intended use of Siemens MultiView WorkStation & INFINITY Network is to act as a communications network, central monitoring device, and remote display for Siemens Patient Monitoring Systems and recorders.

INFINITY VentViewer is an application within the MultiView WorkStation Central Station monitor that presents a subset of data, such as waveforms, parameter values, and selected status messages received from Siemens INFINITY Bedside monitors and their appropriate MIB-interfaced devices. Device messages include device settings, and from certain devices (as specified below) visual and audible indication of alarm status from devices connected to an INFINITY bedside monitor via a Medical Information Bus (MIB) connection. Such devices include:

Siemens SV 300 ventilator
Siemens SV900 ventilator*
Draeger Evita II ventilator
Draeger Evita IV ventilator
Draeger Babylog ventilator
Puritan Bennett 7200 ventilator
Draeger Narkomed II Anesthesia System*
Draeger Narkomed IV Anesthesia System*
Draeger Julian Anesthesia Machine*
Ohmeda 7900 / Modulus CD Anesthesia Machine*

*NOTE: Visual/audible alarm indications are not available from these devices

Assessment of non-clinical performance data for equivalence: Section K

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances: Same as 510(k) K955059

COMPANY CONFIDENTIAL

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2000

Ms. Penelope Greco
Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K003246
Trade Name: Siemens Multiview Workstation and INFINITY Network with the INFINITY VentViewer System
Regulatory Class: III (three)
Product Code: DSI
Dated: November 21, 2000
Received: November 24, 2000

Dear Ms. Greco:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003246

Device Name: Siemens MultiView WorkStation and INFINITY Network

Indications for Use:

Siemens MultiView WorkStation and INFINITY Network are indicated for use as a communications network, central monitoring device, and remote display for Siemens INFINITY patient monitoring systems and recorders.

INFINITY VentViewer is an application within the MultiView WorkStation Central Station monitor that presents a subset of data, such as waveforms, parameter values, and selected status messages received from Siemens INFINITY Bedside monitors and their appropriate MIB-interfaced devices. Device messages include device settings, and from certain devices (as specified below) visual and audible indication of alarm status from devices connected to an INFINITY bedside monitor via a Medical Information Bus (MIB) connection. Such devices include:

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Ohmeda 7900 / Modulus CD Anesthesia Machine *

*NOTE: Visual/audible alarm indications are not available from these devices

MRI Compatibility Statement:
The MultiView WorkStation and INFINITY Network are not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003246